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Attorney Docket No. 2002834-0115

### DECLARATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

### CONDUCTANCE OF IMPROPERLY FOLDED PROTEINS THROUGH THE SECRETORY PATHWAY AND RELATED METHODS FOR TREATING DISEASE

the specification of which (I authorize Choate, Hall & Stewart to check one of the following three choices, and fill in the blanks, if applicable):

\_\_\_\_\_ is attached hereto

X was filed on October 12, 2001 as Application Serial No. 09/976,963 and amended on \_\_\_\_\_ (if applicable).

\_\_\_\_\_ was filed as PCT international application No. \_\_\_\_\_, on \_\_\_\_\_ and was amended under PCT Article 19 on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledged the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s):

Priority Claimed

(Number)	(Country)	(Day/Month/Year/Filed)	Yes	No
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(Number)	(Country)	(Day/Month/Year/Filed)	Yes	No
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I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

<u>09/427,696</u>	<u>October 27, 1999</u>	<u>pending</u>
(Application Serial No.)	(filing date)	(status-patented, pending, abandoned)
 <u>                    </u>	 <u>                    </u>	 <u>                    </u>
(Application Serial No.)	(filing date)	(status-patented, pending, abandoned)

PCT Applications designating the United States:

<u>                    </u>	<u>                    </u>	<u>                    </u>
(PCT Appl. No.)	(U.S.S.N.)	(status-patented, pending, abandoned)

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national filing date of this application.

Provisional Application(s):

<u>                    </u>	<u>                    </u>	<u>                    </u>
(Application Serial No.)	(filing date)	(status)
 <u>                    </u>	 <u>                    </u>	 <u>                    </u>
(Application Serial No.)	(filing date)	(status)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United State Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Post Office Address Same as abovePost Office Address Same as above

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ATTORNEY DOCKET NUMBER: 2002834-0115

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(3)

Applicant: Caplan *et al.*  
Serial No.: 09/976,963  
Filing Date: October 12, 2001  
Title: CONDUCTANCE OF IMPROPERLY FOLDED PROTEINS THROUGH  
THE SECRETORY PATHWAY AND RELATED MEHTODS FOR  
TREATING DISEASE

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, DC 20231

Sir:

WRITTEN ASSERTION OF SMALL ENTITY STATUS  
UNDER 37 CFR §1.27(a)(2)  
SMALL BUSINESS CONCERN

The undersigned hereby asserts entitlement to small entity status as a small business concern under 37 CFR §1.27(a)(2) on behalf of Panacea Pharmaceuticals, LLC.

This assertion is made on the ground that Panacea Pharmaceuticals, LLC is a concern

(a) whose number of employees, including affiliates, does not exceed 500 persons; and

(b) that *has not* assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey, or license, any rights in the above-referenced patent application to any party who does not qualify for small entity status either as a person, a small business concern, or a nonprofit organization under 37 CFR §1.27, as set forth in 13 CFR §121.802.

Respectfully Submitted,

Name: Howard Sosin

Title: President / CEO

Date: 26 Feb 2002

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ATTORNEY'S DOCKET NUMBER: 2002834-0115

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Caplan *et al.*  
Serial Number: 09/976,963  
Filed Date: October 12, 2001  
Title: CONDUCTANCE OF IMPROPERLY FOLDED PROTEINS  
THROUGH THE SECRETORY PATHWAY AND RELATED  
METHODS FOR TREATING DISEASE

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

Sir:

WRITTEN ASSERTION OF SMALL ENTITY STATUS  
UNDER 37 CFR §1.27(a)(3)  
NON-PROFIT ORGANIZATION

The undersigned hereby asserts entitlement to small entity status as a non-profit organization under 37 CFR §1.27(a)(3) on behalf of Yale University.

This assertion is made on the ground that Yale University is either:

- (X) a university or other institution of higher education located in any country;
- ( ) an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 USC §501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 USC §501(a));
- ( ) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 USC §201(i)); or
- ( ) any nonprofit organization, located in a foreign country, that would qualify as a nonprofit organization under paragraphs (b) or (c) above if it were located in this country,

and *has not* assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey, or license, any rights in the above-referenced patent application to any party who does not qualify for small entity status either as a person, a small business concern, or a nonprofit organization under 37 CFR §1.27.

Respectfully Submitted,

Dorothy K Robinson  
Name: DOROTHY K ROBINSON  
Title: VICE PRESIDENT + GENERAL COUNSEL  
Date: 12/19/01

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